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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,249	12/05/2001	Michael John Stephen Austin	S63.2-10014	8321

490 7590 03/03/2005

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

28

Office Action Summary	Application No.	Applicant(s)	
	09/683,249	AUSTIN, MICHAEL JOHN STEPHEN	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28,30,33 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) 4,10-28,30 and 33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/25/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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This application contains claims 4, 10-28, 30 and 33 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-3, 5-9, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vrba (6,168,621). Vrba, in the embodiment of figure 6, discloses a first balloon expandable segment 14 and a first and second self-expanding segments 12, 12. Vrba, in this embodiment, fails to disclose a second balloon expandable segment. However, Vrba teaches that the stent according to the invention may be comprised of more than one balloon expandable part and that any combination of balloon expandable parts and self-expanding parts are within the scope of the invention (col. 2, lines 50-53). It would have been obvious to include more than two balloon expandable parts in the embodiment of figure 6 view of this teaching. Further, it would have been obvious to locate a self-expanding part between the two balloon expandable parts since all of the embodiments disclosed show the self-expanding parts and balloon expandable parts alternating with one another along the length of the stent. Also, Vrba, in col. 2, lines 26-33 indicates that the self-expanding part 12 may be placed in parts of the stent other

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than the proximal end of the stent. The only other parts of the stent that exist are the distal end and the main central part. Thus, it would have been obvious that Vrba teaches locating the self-expanding part 12 in either the distal end or the main central part of the stent. When the self-expanding part 12 is in the main central part of the stent, it is located between two balloon expandable segments as claimed. As to claim 5, the self-expanding part located between the two balloon expandable parts as described above is the claimed intermediate island. As to claim 36, Vrba fails to disclose a protective covering. However, it is old and well known to include coatings on stents in order to obtain the advantage of administering drugs to inhibit restenosis as admitted in paragraph [0003] of applicant's specification. It would have been obvious to include a coating on the Vrba stent so that it too would have this advantage.

Claims 1-3, 5-9, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vrba (6,168,621) in view of Vonesh et al. (WO 00/33770). Vrba, in the embodiment shown in figure 6, fails to disclose a self-expanding segment disposed between first and second balloon expandable segments. However, Vonesh et al., in figure 9, teaches that a self-expanding segment of a stent should be located between balloon expandable

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segments. Note that Vonesh et al. disclose a first balloon expandable segment (e.g. section 56 at the extreme left side of the figure), a second balloon expandable segment (e.g. section 56 at the middle of the figure) and a first self-expanding segment (e.g. the section 58 between the first and second balloon expandable segments). Further, the balloon expandable segments may be not self-expanding as indicated on page 17, lines 5-9. This arrangement has the advantage of programming the prosthesis to have particular flow characteristics and/or to be safely deployed in certain applications where it is not desirable to have the entire device fully dilated (page 17, lines 3-5). It would have been obvious to locate a self-expanding segment between first and second balloon expandable segments in the Vrba stent so that it too would have this advantage. As to claim 2, the sections 56 at the extreme left and right sides of figure 9 of Vonesh et al. (incorporated into the Vrba stent) may be considered to be the claimed first and second balloon expandable segments while the two sections 58 may be considered to be the first and second self-expanding segments which are between the first and second balloon expandable segments. As to claim 3, the section 56 in the middle of the Vonesh et al. stent (incorporated into the Vrba stent) is considered to be the third balloon expandable segment. As to

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claim 5, the self-expanding cells are provided at intermediate islands 58 of Vonesh et al. (incorporated into the Vrba stent) which are surrounded (on both sides) by balloon expandable material.

Claim 38 is allowed.

Applicant's arguments filed Jan. 25, 2005 have been fully considered but they are not persuasive for the reasons set forth above. Each opening of the balloon expandable segments of Vrba extends straight through the sidewall of the stent as is now claimed. The allegation that the balloon expandable cells of Vrba include self-expanding material is unfounded. The balloon expandable part 14 of Vrba requires a balloon for expansion as indicated in col. 1, lines 38-43 and therefore does not include self-expanding material.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
3/1/05



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731